

64. (Withdrawn) The method of claim 48, wherein the airway epithelial cell is in an alkaline solution.

65-141. (Canceled).

### **Remarks**

Claims 1-3, 12-13, 21-23, 37-38, 41-45, 48-52, 58, 61, and 64 are pending. Claims 37-38, 41-45, 48-52, 58, 61, and 64 are withdrawn. Claims 1, 12-13, and 21-22 have been amended. Claims 4-11, 24-36, 39-40, 46-47, 53-57, 59, 60 62, 63, and 65-141 are canceled. Claims 1, 12-13, and 21-22 were amended to more clearly claim what applicants consider to be their invention.

Claims 1, 13, and 22 have been amended to recite the additional molecules ATP; ivermectin;  $\alpha$ ,  $\beta$ -methylene-ATP; benzoyl-benzoyl-ATP; ATP $\gamma$ S; and AMPPNP. Support for these amendments can be found, for example, on page 28, lines 17-20 of the specification. Claims 12 and 21 were amended to correct a typographical error (Zn<sup>+</sup> should have been Zn<sup>2+</sup>, as evidenced throughout the application) and to add the word "or" between the steps recited to further clarify the claims.

Applicants note that none of these amendments limit the claims from their original scope and none of the amendments were made for reasons related to patentability.

### **Response to Restriction Requirement**

In the Office Action mailed July 11, 2006, the claims were divided into six groups: Group I, claims 1-3, 12-13, 21-23 and 34 drawn to a method of increasing Ca<sup>+2</sup> levels in an airway epithelial cell or a method of treating airway disease comprising administering Zn<sup>+2</sup>; Group II, claims 37-38, and 41, drawn to a composition comprising zinc, saline, low Na<sup>+</sup>, enriched Ca<sup>+2</sup>, and alkaline pH; Group III, claims 42-43, drawn to a method of treating a bacterial infection or reducing inflammation in a subject comprising administering a composition comprising zinc, saline, low Na<sup>+</sup>, enriched Ca<sup>+2</sup>, and alkaline pH; Group IV, claims 44, drawn to a method of treating polycystic kidney disease in a subject comprising administering a

composition comprising zinc, saline, low Na<sup>+</sup>, enriched Ca<sup>+2</sup>, and alkaline pH; Group V, claim 45, drawn to a method of treating endocrine disorder in a subject comprising administering a composition comprising zinc, saline, low Na<sup>+</sup>, enriched Ca<sup>+2</sup>, and alkaline pH; and Group VI, claims 48-52, 58, 61 and 64, drawn to a method of screening for an airway epithelial Ca<sup>+2</sup> entry channel agonist.

In response, applicants elect Group I, claims 1-3, 12-13, and 21-23, with traverse. Claim 34 was cancelled as it depended from a canceled claim.

37 C.F.R. § 1.475 provides that national stage applications shall relate to one invention or to a group of inventions so linked as to form a single general inventive concept. Such inventions possess unity of invention. The requirement of a single inventive concept is fulfilled when there is a technical relationship within the claimed subject matter involving one or more of the same or corresponding special technical features. The special technical feature must define a contribution that the claimed subject matter makes over the prior art.

Applicants note that the claims all include administering zinc to a cell, thereby increasing cytosolic Ca<sup>2+</sup> levels in the cell, and treating disease, and that this constitutes a special technical feature that defines a contribution that the claimed subject matter makes over the prior art.. Accordingly, Applicants submit that all of the pending claims possess unity of invention. The Examiner cited U.S. Patent 5,840,278, and stated that the actual method step of contacting P2X receptors on the cell or contacting cells in the trachea, bronchi, bronchioles, or alveoli with a composition that contains Zn<sup>+2</sup> is not a technical feature that defines a contribution over the prior art. However, U.S. Patent 5,840,278 discloses administering zinc in a vitamin and mineral blend that contains many other substances as well. Furthermore, U.S. Patent 5,840,278 discloses administering zinc in the amount of 35 mg. The present invention discloses administering zinc in a preferable amount of 20-40 μM (1.3-2.6 mg). The present specification states that, “[t]he dosage should not be so large as to cause adverse side effects...” (Page 25, lines 21-22). The amounts shown in U.S. Patent 5,840,278 are more than ten times the amounts shown to be effective to increase cytosolic Ca<sup>2+</sup> levels in the present specification. Therefore, U.S. Patent 5,840,278 does not anticipate the instant claims, and the instant claims teach a technical feature

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that defines a contribution over the prior art. Because all of the pending claims possess unity of invention, the present restriction requirement is improper and must be withdrawn. Accordingly, applicants respectfully request rejoinder and examination of all of the claims.

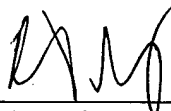
Favorable consideration of claims 1-3, 12-13, and 21-23 is earnestly solicited.

Pursuant to the above amendments and remarks, reconsideration and allowance of the pending application is believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issue.

No fees are believed to be due at this time; however, the Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

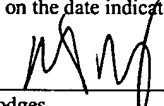


Robert A Hodges  
Registration No. 41,074

NEEDLE & ROSENBERG, P.C.  
Customer Number 23859  
(678) 420-9300  
(678) 420-9301 (fax)

**CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8**

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8/11/2006